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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/451,180 11/29/99 FISCHER

W 29473/10458

EXAMINER

HM12/0118

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GHAI, T. T.

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

01/18/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/451,180

Applicant(s)

FISCHER ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 29 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 16-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

### DETAILED ACTION

The receipt is acknowledged of applicants' declaration and establishment of small entity, filed 1/18/2000; second preliminary amendment and I.D.S., both filed 5/9/2000; English translation and request for extension of time, filed 5/10/2000; and status letter, filed 11/27/2000.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does include description of the filler, skin protective substances and the tackifiers in a manner that allow one skilled in the art to practice the invention without undue experimentation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 18, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 18, the claim is confusing as it recites "skin protective substances", what are these skin protective substances?.

Regarding claim 25 recites the limitation "dry" in claim 19. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 18-20, 22, 23, 25, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,965,155 ('155).

US '155 disclosed a transdermal patch for the treatment of migraine, said patch comprising contact adhesive layer comprising clonidine in base comprising copolymer of 2-ethylhexyl acrylate and vinyl acetate. The adhesive layer further comprising filler, tackifier and plasticizer. The transdermal plaster comprising an impermeable backing and a protective layer, which is removed prior to use, such a layer is made of siliconized paper. The structure is inherently multi-layered. The adhesive layer has weight per unit area of 125 mg/m<sup>2</sup>. See the

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abstract; col.1, lines 8-15, 54; col.3, lines 12-43, 58-62; col.4, lines 5-9, 30-37, 65-67; col.5, lines 16-17.

7. Claims 1, 19, 24 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,869,089 ('089).

US '089 disclosed a transdermal delivery device to treat drug addiction, said TTS comprising drug adhesive reservoir containing clonidine and the copolymer of ethylhexyl acrylate and vinyl acetate; backing of polyester; and silicone based release liner. The TTS is inherently multi-layered. See abstract; col.1, lines 56-67; col.2, lines 1-11; col.3, lines 14-20, 34, 40-42; col.4, lines 12-35.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '155 or US '089, each standing by itself or in combination with US 6,024,976 ('976).

The teachings of US '155 and US '089 are discussed under 102 rejection above. It is within the skill in the art to select different materials for the backing and protective layers such as plastic, polyester, woven and non-woven fabric, and they all well known in the art. It is within the skill in the art to select optimal parameters such as ratios and weight percents of components as well as determining the dose of delivering a medication in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the weight percents of clonidine and its delivery rate instantly claimed are not considered critical absent evidence showing unexpected and superior results.

US '976 is disclosing a transdermal delivery system comprising adhesive matrix comprising 2-ethylhexyl acrylate and copolymer of vinyl acetate comprising clonidine in an amount of 0.3 to 30%; tackifying agent; backing made of plastic film or polyester; and a release liner. See acol.2, lines 53-64; col.3, lines 1-8; col.4, lines 45-48; col.11, line 11; col.12, line16; col.32, lines 41-45; col.33, lines 15-16; col.34, lines 31-44

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce the claimed transdermal structure comprising adhesive matrix and plastic backing and adjust amount of clonidine in order to treat vasodilatation with reasonable expectation of success of treating migraine and other disorders.

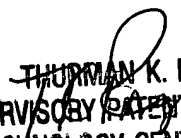
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali  
Examiner  
Art Unit 1615

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



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Receipt is acknowledged of applicants Status Letter filed . The application is assigned to examiner *I. GHALI* whose telephone number is 703-305-4048 . If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on 703-308-2927. The application is assigned to Art Unit 1615. Any inquiry of a general nature of this application should be directed to the Group receptionist whose telephone number is 703-308-1235.

This application was filed *11/19/99* . It is expected that an action in this case will be mailed within *1 week* from the mailing of this letter.

**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

Thurman K. Page  
Supervisory Patent Examiner  
Group 1600 Art Unit 1615